

Toxicology Excellence for Risk Assessment



TERA

a nonprofit corporation dedicated to the
best use of toxicity data for risk values

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SFUND RECORDS CTR
47563

September 10th, 1997

Mr. Charles Berrey
Remedial Project Manager
U.S. EPA, Region 9
75 Hawthorne Street
San Francisco, CA 94105

Dear Mr. Berrey:

I thank you for your letter of July 17th, transmitting comments on the perchlorate draft study protocols. The U.S. Air Force, the Perchlorate Study Group and *TERA* considered these comments (and others) as final protocols were developed. Final protocols will be placed on the *TERA* web page (www.tera.org/news) after these studies are started. We anticipate periodic updates of these studies and related data to be placed on this web page also.

The U.S. Air Force and the Perchlorate Study Group wish to peer review a revised perchlorate RfD at one of the quarterly meetings of *TERA*'s International Toxicity Estimates for Risk (*ITER*) project. The target date for this external peer review is
→ September 1998.

I attach a two page description of the *ITER* peer review process. If you wish to participate as a reviewer, a self nomination process exists (see www.tera.org/iter). However, *TERA* has also invited a number of scientists to participate, including members of NCEA, Cincinnati. All reviewers, whether self-nominated or invited must be approved by *TERA*'s Board of Trustees. A current list of reviewers can be found at www.tera.org/iter. Please call with any questions.

Sincerely,

Michael L. Dourson, Ph.D., DABT
Director

Cc: Major Dan Rogers, US Air Force
Michael Girard, Perchlorate Study Group



***TERA* Statement of Purpose**

Toxicology Excellence for Risk Assessment (***TERA***) is a non-profit, 501(c)(3) corporation organized for scientific and educational purposes. Our mission is to protect public health by developing and communicating risk assessment values, improving risk methods through research, and educating the public on risk assessment issues. Specific activities of ***TERA*** include:

- establishing high quality risk assessment values for human health and the environment through the Verifiable Estimates for Risk Assessment (***VERA***) program;
- compiling and distributing peer reviewed risk values to the international user community through the International Toxicity Estimates for Risk (***ITER***) database;
- sponsoring expert **peer review** of risk values;
- improving the underlying methods for human and ecological risk assessment through **research** and publication;
- educating diverse groups on risk assessment issues, through training courses, scientific support and the State Hazard Evaluation Lending Program (**State HELP**);
- facilitating improved risk assessment and **management decisions** among industry and government groups through informed and neutral guidance.

TERA is a non-profit corporation organized under section 1702.01 of the Ohio Revised Code, and is classified as a 501(c)(3) organization under the Internal Revenue Service Code. Corporations, companies, associations, individuals and foundations may support the work of ***TERA*** through tax-deductible contributions.



International Toxicity Estimates for Risk (ITER) Peer Review Program: Roles of Participants

TERA

Toxicology Excellence for Risk Assessment (TERA) is a non-profit [501(c)(3)] organization dedicated to the best use of toxicity data for risk assessment. TERA has developed the ITER peer review program to provide a mechanism for any organization (academia, consulting, government, industry, nonprofit) to have their chemical assessments and risk values undergo an independent peer review by risk assessment experts. The goal of the program is to support the development of scientifically sound risk values and upon approval, share these values with the greater risk assessment community and the public through the ITER database. TERA runs the peer review program at cost, charging sponsors a fee for each review. There is no other financial support for the ITER Peer Review program.

Peer Reviewer (Panel Member)

Peer reviewers are expert scientists in risk assessment and related disciplines. Their nominations are reviewed and approved by the TERA Board of Trustees, after which they are included in the roster of potential peer reviewers. **Each reviewer is an unpaid volunteer** who agrees to participate and represent his or her personal scientific opinion. TERA staff select 10-12 scientists from the roster for each meeting, striving for a balance of organizational affiliation and necessary specific expertise. For each meeting the selected peer reviewers must sign a conflict-of-interest certification. The peer reviewers review the assessment packages, prepare pre-meeting comments and come to the meeting prepared to discuss the assessment. Reviewers are asked to be explicit in identifying issues and proposed strategies to resolve them.

TERA reimburses some travel costs at this time, primarily for peer reviewers from government and non-profit organizations.

Ad Hoc Peer Reviewer

Occasionally, a particular issue or assessment may benefit by the participation of an additional reviewer who is not on the regular roster of ITER Peer Reviewers, but has some specific knowledge or expertise which is needed. These reviewers serve as volunteers, but may have their expenses paid by TERA.

Non-Attending Peer Reviewer

Occasionally, a selected peer reviewer is not able to attend the meeting but his or her expertise is considered critical. In that case, the individual provides a written review which is shared with the panel members. These reviewers may be regular or ad hoc peer reviewers.

Chair

The chair is a panel member who structures and moderates the discussion to make the most efficient use of the panel's time. The Chair leads the panel through a series of discussion topics to evaluate both the hazard identification and dose-response components of the assessment. The Chair polls the panel for consensus.



Sponsor

The sponsor is the organization that has contracted with *TERA* to have the review conducted. For each assessment the sponsor prepares a package to document and support the proposed risk value and the scientific rationale behind it. They provide this package to *TERA* in advance of the meeting for *TERA* to ensure its completeness and quality so that the review will be effective. The review package includes a supporting document, which includes a description and evaluation of all relevant literature and the rationale for their risk value, copies of critical studies and a list of issues for discussion.

Invited Expert

On some occasions a sponsor may invite additional experts in a particular field to attend the meeting and be available to answer panel questions. These experts may be paid by the sponsor, in which case this will be disclosed at the meeting. The inclusion of invited experts can allow the panel members to resolve issues quickly and avoid having to ask the sponsor to consult with experts post-meeting and return for subsequent reviews.

Observer

Meetings are open to observers. To during the discussion of each assessment a short period is set aside for individuals make brief (< 5 minutes) technical comments. Space is limited and observers are asked to register in advance. A registration fee covers the cost of review materials and refreshments.

Media

Members of the media are welcome to attend any meeting as observers. They are asked to abide by *TERA*'s Policy on Meeting Notes (shown below) with regard to identification of panel members with specific comments.

***TERA* Note Taker**

TERA provides a scientist to take notes of discussions and conclusions and provide a draft meeting summary to the sponsors and peer reviewers for comment. The final meeting summary is subsequently made available on *TERA*'s home page and by request.

***TERA* Policy on Meeting Notes**

After each meeting *TERA* writes a summary of the technical discussion and conclusions, which is then made available to any interested party. To foster a full and open discussion, *TERA*'s policy is to not identify reviewers' names or affiliations with particular comments; rather a summary of the discussion is presented and a list of reviewers is provided. The purpose of this policy is to allow the reviewers to express their opinions openly without fear of being quoted incorrectly or out of context. The final consensus opinion of the group as a whole is the important outcome of this process. *TERA* asks that all participants, including reviewers, sponsors, observers and media extend this same courtesy.